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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/549,498 | 08/14/2006 | Colin G. Caro | DEHN 2 00008 | 7739 |
| 27885 | 7590 | 08/11/2008 | EXAMINER | |
| FAY SHARPE LLP 1100 SUPERIOR AVENUE, SEVENTH FLOOR CLEVELAND, OH 44114 | | | WOLF, MEGAN YARNALL | |
| ART UNIT | PAPER NUMBER | | | |
| | | 3738 | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|------------------------------------|
| Office Action Summary | Application No. 10/549,498 | Applicant(s) CARO ET AL. |
| | Examiner MEGAN WOLF | Art Unit 3738 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 09 May 2008.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-3,8-13 and 28-33 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-3,8-13 and 28-33 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/136/08)
Paper No(s)/Mail Date 050908

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____

5) Notice of Informal Patent Application

6) Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 5/9/08 have been fully considered but they are not persuasive. Houston et al. 2002/0179166 as a whole discloses the invention as claimed. While Applicant's arguments regarding figures 1-4b of Houston are persuasive, arguments regarding figure 5 are not persuasive. Figure 5 of Houston illustrates an embodiment wherein the mesh is longitudinally coiled and has a circular cross-section that induces a helical flow pattern upon a conduit within it. Houston par.10 discloses that the helix angle may be between 5 and 50 degrees and par. 62 describes that the helix angle should be chosen such that it minimizes pressure drop and turbulent kinetic energy and states that this minimization occurs at a helix angle of about 8 degrees. Therefore, as the helix angle is disclosed by Houston to be less than or equal to 45 degrees, and the embodiment of figure 5 illustrates a flow lumen free of ribs or grooves wherein the center line of the flow lumen follows a substantially helical path as well as an amplitude of the helix less than or equal to one half of the internal diameter of the tubing portion, Houston anticipates claim 1. While Applicant also argues that there is no line of sight along the inside of the tubing shown in fig.5, this limitation is not in the claim. Further, Houston's fig. 5 is simply an example of the shape of the device and if the helix angles described by Houston were to be illustrated with the desired helix angle disclosed in par.62, the tubing would provide line of sight along its inside.
2. Applicant argues that the provisional nonstatutory double patenting rejection is premature. The Examiner recognizes that copending application 10/549,211 is not

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patented which is why the rejection is provisional. Because the amended claims are not patentably distinct from the copending application, the provisional double patenting rejection remains.

Information Disclosure Statement

3. Document AS submitted in the IDS filed 12/6/05 has been considered.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 10/549211. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims only differ in terminology and intended use. The independent claim in both applications includes a

tubular portion substantially free of ribs or grooves, wherein the center line of the lumen follows a helical path with a helix angle less than or equal to 65° and the amplitude of the helix is less than or equal to one half of the internal diameter of the tubing portion. The dependent claims are identical aside from the preamble which includes intended use of the product.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-3, 8-11, 28, 29, 32, and 33 are rejected under 35 U.S.C. 102(e) as

being anticipated by Houston et al. 2002/0179166.

8. Re claims 1-3, Houston discloses a graft comprising flow tubing having a tubing portion defining a flow lumen, the flow lumen of the tubing portion being substantially free of ribs or grooves (par.51), wherein the centre line of the flow lumen follows a substantially helical path with a helix angle less than or equal to 45° (par.10), and wherein the amplitude of the helix is less than or equal to one half of the internal

diameter of the tubing portion (fig.5; par.10), and wherein the amplitude of the helical center line divided by the internal diameter of the tubing is at least 0.05 (fig.5).

9. Re claims 8 and 28, see par.10 and 62, ll.18-20.
10. Re claims 9 and 29, see pars.20 and 51.
11. Re claims 10 and 11, see fig. 4A for an example wherein the mesh may extend partially and substantially over tubing 3.
12. Re claims 32 and 33, see par.53.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 12 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houston et al. 2002/0179166. Houston discloses the invention substantially as claimed and as discussed above. Houston does not disclose a graft wherein the center line of the tubing portion follows a substantially helical path about an axis that is curved. However, providing a curved graft would have been obvious to one of ordinary skill in the art at the time of the invention because vessels that the graft replaces are typically curved, and in order to bypass blockage in a vessel the graft would be required to be curved. Also, the graft of Houston is disclosed as being made from flexible materials and is therefore capable of being curved during use.

15. Claims 13 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houston et al. 2002/0179166 in view of Healy et al. 5,670,161. Houston discloses the invention substantially as claimed. However, Houston does not disclose a graft comprising a pharmaceutical coating.

Healy discloses a stent graft, in the same field of endeavor, comprising a drug coating for the purpose of positively affecting healing at the site of implantation (col.10, II.10-13).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to add a pharmaceutical coating to the graft disclosed by Houston in order to induce healing at the site of implantation, as taught by Healy, col.10, II.10-13. Further, it is well known in the art to coat a graft with pharmaceuticals to prevent thrombosis, etc.

16. Claims 1-3, 8, 9, 12, 28-30, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over FR 2248015 to Societe Rhone-Poulenc Industries (submitted in IDS, hereafter referred to as FR'015). FR'015 discloses the invention substantially as claimed including a graft comprising flow tubing having a tubing portion 3 defining a flow lumen, the flow lumen of the tubing portion being substantially free of ribs or grooves, wherein the center line of the flow lumen follows a substantially helical path, wherein the amplitude of the helix is less than or equal to one half of the internal diameter of the tubing portion, and wherein the amplitude of the helical center line divided by the internal diameter of the tubing is at least 0.05 (fig.2). While the exact helix angle can not be determined from the figure and is not explicitly disclosed in the specification, the

helix angle in fig.2 appears to be approximately 55 degrees rather than the claimed 45 degrees. However, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), MPEP 2144.05 II A). Because FR'015 illustrates an exemplary helix angle of about 55 degrees, it would have been obvious to one of ordinary skill in the art at the time of the invention to decrease the helix angle as necessary for its intended use and desired outcome while still providing an angle greater than zero to prevent kinking.

17. Re claims 9, 12, 29, and 30, French '015 further teaches that the tubing is of substantially circular cross-section and the center line of the tubing portions follows a substantially helical path about an axis which is curved (fig.2).

18. Re claims 32 and 33, the tubular wall in fig.2 is designed to resist the reduction of amplitude of the helical center line shown in fig.3.

Conclusion

19. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 5/9/08 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MEGAN WOLF whose telephone number is (571)270-3071. The examiner can normally be reached on Monday-Friday 7:00-4:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. W./
Examiner, Art Unit 3738
8/5/08

/Bruce E Snow/
Primary Examiner, Art Unit 3738